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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,414	THEOBALD ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-44* is/are pending in the application.

4a) Of the above claim(s) *13-24 and 34-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-12 and 25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/08 has been entered.

Applicant's amendment in the reply filed on 10/16/08 is acknowledged, with the cancellation of Claim 4. Claims 1-3, and 5-44 are pending. Claims 13-24, and 34-44 are withdrawn as they are directed toward non-elected invention groups. **Claims 1-3, 5-12, and 25-33 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Objections

Claim 10 is objected to because of the following informalities: Claim 10 recites "S-I-S block copolymers". It is improper to recite the abbreviation in the claims, and Applicant is required to spell out the full name of the abbreviation.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-12, and 25-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the following limitations, and there is insufficient antecedent basis for these limitations in the claim.

"the treatment of colds" in claim 1, lines 1 and 7;

"the occurrence of" in claim 1, line 10;

"the water content" in claim 1, line 15; claim 25, line 1;

"the proportion" in claim 2, line 1; claim 11, line 2; claim 26, line 1; claim 32, line 1;

"the overall proportion" in claim 6, line 1; claim 8, line 1; claim 28, line 1; claim 29, line 1; claim 31, line 1.

Claim 1 recites "cyclodextrin derivatives" (line 9); and "silicid acid derivatives" (line 9); claim 3 recites "cellulose derivatives (line 3)…starch derivatives (line 5); claim 27 recites "cellulose derivatives" in lines 1-2. The phrase "…derivatives" is unclear. It is unclear what modifications of the compound would be encompassed in the derivatives. The derivatives can be any structure, and any modification. Thus, it is unclear what modifications and derivatives are encompassed by the claimed "…derivatives".

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7-11, 25-27, and 31-33 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al (US 6,090,403), in view of Hidaka et al (US 6,319,515), further in view of Gal-Fuzy et al (Cyclodextrin-stabilized volatile substances for inhalation therapy, Pharmazie 39 (8), 1984, pp. 558-559).

Block et al teach a skin patch for the relief of colds (claim 1). The patch includes an underlying layer of non-irritating medical grade pressure-sensitive adhesive, and a foraminous upper carrier layer to which the decongestant-containing ointment is applied (col 5, lines 4-10). The patch is capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch (col 2, lines 52-60). The expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant agent. It also helps to prolong the useful life of the product (col 2, lines 25-30). A variety of well known therapeutic agents that have a decongestant or analgesic action can be employed, examples include oil of menthol, camphor etc (col 2, lines 60-65). A hydrophobic vehicle comprises a pressure-sensitive adhesive matrix (col 3, lines 18-21). Other adhesives such as acrylic polymeric adhesives (a type of polyacrylates), and vinyl acetate copolymers (the same as

polyvinyl acetate), can be used (col 3, lines 23-26). The skin patch includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya (a type of gum, hydrophile polymer, having adsorbent effect), carboxymethyl cellulose (cellulose derivative), polyacrylamide, and polyacrylic acid (claim 10). The patch also includes a humectant (a type of moisturizer, adjuvant) comprising a polyhydric alcohol (claim 6), and the antitussive is camphor or menthol (claim 40).

Block et al do not teach the specific claimed amounts of the followings: water content of the matrix, hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, and adjuvants; neither do Block et al teach the incorporation of cyclodextrin into the composition.

Hidaka et al teach an isosorbide dinitrate-containing patch having an adequate degree of adhesive strength and hardly giving pain on the removal of an applied patch (col 2, lines 37-42), and it is good in balance between adhesivity and skin irritation (col 1, lines 60-62). Hidaka et al also teach the function of a patch of the present invention can be further stimulated by suppressing the water content of the adhesive composition below a specified level. In particular, when the water content of the adhesive composition is 0.5% or less, more preferably 0.2% or less by weight, the remarkable function will be attained (col 12, lines 37-44).

Gal-Fuzy et al teach cyclodextrin-stabilized volatile substances for inhalation therapy (see Title). Gal-Fuzy et al teach Diapulmon which comprise camphor, 1-menthol, eucalyptus oil and quinine dissolve in sunflower oil is marketed ampoules of 2 ml but utilized almost exclusively for inhalation therapy. Complexing the active ingredients of Diapulmon with β-cyclodextrin, a stable non hygroscopic microcrystalline substance is obtained. When this powder sprinkled on

hot water, the included volatile compounds are gradually released and the desired pharmacological effect can be brought about (see Abstract).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to control the water content being less than 5% by weight from Hidaka et al since Hidaka et al teach when the water content of the adhesive composition is 0.5% or less, more preferably 0.2% or less by weight, the remarkable function will be attained.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to incorporate cyclodextrin from Gal-Fuzy et al since Gal-Fuzy et al teach using cyclodextrin to stabilize volatile substance for inhalation to provide gradual release of the desired pharmacological effect.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of

scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amount of hydrophile polymer, essential oil, pressure-sensitive adhesive polymer, and adjuvants, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal amount of components because the amount of the claimed components are art-recognized result effective variables because they have the ability to form a patch, which would have been routinely determined and optimized in the pharmaceutical art.

The intended use of the composition in quotation mark was analyzed for patentable weight. It is deemed that they 'breath life' into the claims in that the prior art product must not be precluded to use for those purpose. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims. More specifically, it is deemed that the essential oils menthol and camphor are inhalable as a decongestant; the hydrophyile polymer gum karaya could deliver the essential oils menthol and camphor for the

treatment of colds and prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least one essential oil phase; and the pressure-sensitive adhesive polymer could adhere patch to the skin.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1-3, 5-11, 25-29, and 31-33 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al, Hidaka et al, and Gal-Fuzy et al as applied to claims 1-3, 7-11, 25-27, and 31-33 above, and further in view of Borisy et al (US 2002/0165261).

The teachings of Block et al, Hidaka et al, and Gal-Fuzy et al are set forth above and applied as before.

The combination of Block et al, Hidaka et al, and Gal-Fuzy et al do not specifically teach an emulsifying substance in the composition.

As evidenced by Borisy et al, examples of ointment bases are beeswax, paraffin, cetyl palmitate, vegetable oils, sorbitan esters of fatty acids Span), polyethylene glycols, and condensation products between sorbitan esters of fatty acids and ethylene oxide (e.g., polyoxyethylene sorbitan monooleate) (the same as Tween 80) (thus sorbitol ether of polyoxyethylene).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use an emulsifying substance such as Tween 80 in the

ointment of Blocket al in order to form an emulsion, and it is well known in the art that Tween and Span are commonly used emulsifying substance in forming an emulsion such as ointment.

Claims 1-3, 5-11, and 25-33 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al, Hidaka et al, Gal-Fuzy et al, and Borisy et al as applied to claims 1-3, 5-11, 25-29, and 31-33 above, and further in view of Oh (KR 2003021698 A).

The teachings of Block et al, Hidaka et al, Gal-Fuzy et al, and Borisy et al are set forth above and applied as before.

The combination of Block et al, Hidaka et al, Gal-Fuzy et al, and Borisy et al do not specifically teach the incorporation of pine oil into the essential oil.

Oh teaches an aromatherapeutic agent composition comprising pine oil, and other essential oils for treating cold (see Abstract, the rejection is based on the Abstract, full translation has been ordered).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the pine oil from Oh in Block et al since Oh teaches treating cold with aromatherapeutic agent pine oil, therefore one of ordinary skill in the art would have been motivated to make the modifications by incorporating pine oil into the essential oil of Block et al to obtain additive cold-treating effect.

Claims 1-3, 7-12, 25-27, and 31-33 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al, Hidaka et al, and Gal-Fuzy et al as applied to claims 1-3, 7-11, 25-27, and 31-33 above, and further in view of Merkle et al (US 5,527,536).

The teachings of Block et al, Hidaka et al, and Gal-Fuzy et al are set forth above and applied as before.

The combination of Block et al, Hidaka et al, and Gal-Fuzy et al do not specifically teach the patch has a detachable protective layer.

Merkle et al teach a patch for controlled release of readily available volatile active substances to the skin (thus a skin patch), the patch comprising a back layer, and bonded to it, a water-insoluble adhesive film consisting of a pressure-sensitive fusion adhesive, plus a detachable film covering the adhesive film (see Abstract). Merkle et al also teach the skin patch is covered with a protective film, which is removed by peeling it off from the reservoir layer before the use of the patch, that is before application of the patch on the skin (col 1, lines 15-21). Merkle et al further teach that the patch is characterized in that the pressure-sensitive fusion adhesive contains a triple-block copolymer of polystyrene block copoly (ethylene/butylenes) block polystyrene (synthetic rubbers) at a concentration of 10-80% by wt., and an active substance which, at the temperature at which the adhesive bonds, is a readily volatile liquid, and which is present at a concentration of 2.5to 25% by wt (see Abstract). Merkle et al further teach the invention has higher liberation rates, the amount of active ingredients can be reduced without lowering the releasing capacity of the patch. The technical expenditure and consequently the cost of the patch can be kept low by saving solvent, additional reservoir and control layers, as well as active ingredient (col 5, lines 27-55).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the detachable protector layer from Merkle et al since Merkle et al teach the invention has higher liberation rates, low amount of active ingredients, and low cost.

Since both of the compositions yielded beneficial results in skin patch, one of ordinary skill in the art would have been motivated to make the modifications.

Applicant's argument regarding the pot life and shelf life of Block et al (page 14, 3rd paragraph) is not convincing. When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. It appears that Applicant meant to present unexpected results of the current invention. It is noted that according to MPEP 716.02 (a), a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. Applicants need to further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte* The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991).

Applicant's argument regarding there is no teaching or suggestion of low water content in Block et al (page 15, last paragraph; page 16, first two paragraphs) is convincing. Thus reference Hidaka et al is introduced.

Applicant's arguments with respect to the references Kelly and Kamiya et al have been fully considered and are persuasive. Therefore, the rejections over Kelly and Kamiya et al have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gal-Fuzy et al, Borisy et al, and Oh.

/Qiuwen Mi/

Examiner, Art Unit 1655